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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,547	10/26/2005	Harvey Kaplan	1658-8/AMK	1415
7590 08/18/2010				
Adrian M Kaplan Dimock Stratton 20 Queen Street West Suite 3202 PO Box 102 Toronto Ontario M5H 3R3, CANADA			EXAMINER AUDET, MAURY A	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 08/18/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/524,547

## Applicant(s)

KAPLAN ET AL.

## Examiner

MAURY AUDET

## Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/14/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's arguments, amendments and filing of the RCE are acknowledged.

As noted previously:

The Examiner thanks Applicant for the concise analysis of the invention, and identification of the vacuum step as the point of novelty, upon which the analysis below now turns.

The present application has been transferred from former Examiner Young to the present Examiner.

#### ***Election/Restrictions-Previous***

As noted previously, Applicant's election without traverse of Group I, claims 1-6, in the reply filed on 4/16/07, is acknowledged. The remaining claims have been cancelled.

#### ***Claim Rejections - 35 USC § 103-Vacated***

Applicant's new arguments of record, in combination with the previous arguments, have been fully considered and are deemed persuasive, at the present time.

#### ***Claim Rejections - 35 USC § 112 2nd***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the following phrase has been added: "whereby a stable ketoamine derivative is formed".

What is meant by stable? The specification describes:

[0004] *Amino groups in dry proteins are present in their protonated form, and for glycation to take place, the reaction would have to involve these protonated amino groups. On the basis of current theory, a protonated amino group in solution does not react with the aldehyde form of a reducing sugar. Furthermore, there is no known theory that predicts that if a mixture of a protein and reducing sugar in the dry state were subjected to a vacuum that a water-stable glycosylated derivative would be formed. The fact that extensive glycation of proteins does occur in the lyophilized state under vacuum with heating demonstrates that the protonated amino group does indeed react. Therefore, there are two novel theoretical features to the discovery that lyophilized proteins can be efficiently glycosylated in vacuo in the dry state: 1. A protonated amino group will react with a sugar aldehyde group in vacuo. 2. A ketoamine derivative is formed which does not rapidly revert to the free amine and sugar when placed in aqueous solution.*

It is suggested Applicant amend the claims to delete the term "water" and insert the term -- **water-stable**-- to distinctly claim the invention. Or address what stable is meant in it's context as claimed.

What is meant by "ketoamine derivative"? Alone or as part of the protein still? The abstract describes:

It has been discovered that facile glycation of proteins can be achieved by copolyphilization of a protein with a reducing sugar, subjecting the lyophilized mixture to a vacuum (10 to 50 millitor) and incubating at an elevated temperature (50 to 100.degree. C.) for 1 to 24 h. A stable ketoamine derivative is formed **with amino groups in the protein** and no advanced glycation end products (browning reaction) are observed, as is the case with aqueous

glycation procedures.

And, again in the specification para 4:

[0004] *Amino groups in dry proteins are present in their protonated form, and for glycation to take place, the reaction would have to involve these protonated amino groups. On the basis of current theory, a protonated amino group in solution does not react with the aldehyde form of a reducing sugar. Furthermore, there is no known theory that predicts that if a mixture of a protein and reducing sugar in the dry state were subjected to a vacuum that a **water-stable** glycated derivative would be formed. The fact that extensive glycation of proteins does occur in the lyophilized state under vacuum with heating demonstrates that the protonated amino group does indeed react. Therefore, there are two novel theoretical features to the discovery that lyophilized proteins can be efficiently glycated in vacuo in the dry state: 1. A protonated amino group will react with a sugar aldehyde group in vacuo. 2. A ketoamine derivative is formed **which does not rapidly revert to the free amine and sugar when placed in aqueous solution.***

Based on the specification it would appear the latter, and to more distinctly claim the invention the Examiner suggests the phrase --**with amino groups in the protein, which does not rapidly revert to the free amine and sugar when placed in aqueous solution**-- be inserted after the term "derivative".

Thus leaving the amended claim 1, newly added phrase to be:

--**water-stable glycated derivative with amino groups in the protein, which does not rapidly revert to the free amine and sugar when placed in aqueous solution**--

#### *Allowable Subject Matter*

The amendments to the above would likely receive favorable consideration. The determination of allowability of the amended method will remain centered on the final updated search of the art as to whether there any teaching or predictability exists as to using

lyophilisation (vacuum) to achieve glycation of a protein (the central advancement, as noted by Applicant on page 4, para 2 of the present response).

### *Conclusion*

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 7/31/10

/Maury Audet/  
Examiner, Art Unit 1654